K043465
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AUG 1 8 2005

510(k) SUMMARY

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-8333 / 1-800-633-0960

D. Company Facsimile: 719 442 2248

E. Contact Person: Adrian Elfe
Vice President
Quality Assurance & Regulatory Affairs Compliance

DEVICE IDENTIFICATION

A. Device Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter

B. Device Common Name: Laser Catheter

C. Classification Name: Catheter, Peripheral, Atherectomy

D. Device Class: Class II (per 21 CFR 870.4875)

E. Device Code: MCW

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics CLiRpath excimer laser catheters for peripheral use, cleared to market under 510(k) K040067, serve as predicate to the 2.5 mm Turbo CLiRpath Excimer Laser Catheter.

DEVICE DESCRIPTION

Spectranetics' laser atherectomy catheters, including the 2.5 mm Turbo CLiRpath catheter for peripheral use, consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. The 2.5 mm Turbo catheter is designed for "over-the-wire" interventional techniques. Laser energy impinged on a blockage ablates, or debulks, the lesion material re-establishing blood flow within the vessel, and permitting placement of devices used in vascular interventions.

The Spectranetics Turbo laser catheter is supplied with a tip diameter of 2.5 mm, appropriate for interventional use in the peripheral vasculature of the leg.

INTENDED USE

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

COMPARISON TO PREDICATE DEVICES

The Spectranetics 2.5 mm Turbo Excimer Laser Catheter for peripheral use is substantially equivalent in form, fit, and function to other Spectranetics CLiRpath laser catheters, which received market clearance under section 510(k) rules. The 2.5 mm Turbo catheter is an addition to the CLiRpath line of catheters, with the following enhancements.

Increased lubricity
Improved efficiency in energy delivery of 308 nm laser light
Continuous "on" capability

The 2.5 mm Turbo laser catheter consists of a piece of tubing with a working length of approximately 110 cm, and a diameter of 2.5 mm. The catheters communicate excimer laser energy at 308 nm to an occlusion within a patient's targeted peripheral artery. Communicated energy disrupts occlusive material, such as arterial plaque, and permits its removal via the patient's endoreticular system. The pathway opened by either the predicate device or the Turbo catheter, facilitates subsequent placement of other devices and interventions, and re-establishes blood flow within the diseased vessel.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility of both component materials and the finished 2.5 mm Turbo catheter have been confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated, and, in addition, visually verified for 100% of Spectranetics devices prior to transfer to finished goods inventory.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All CLiRpath excimer laser catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

NON-CLINICAL STUDIES

Spectranetics confirmed safety and equivalent efficacy in the peripheral anatomy for the 2.5 mm Turbo laser catheter using a porcine model, in accord with a protocol compliant with good laboratory practices (GLP's). No complications were noted during treatment of the iliac and femoral arteries in the animal model. Histological evaluation of harvested arterial segments showed no deleterious tissue damage after exposure to the 2.5 mm Turbo catheter operating at maximum energy parameters. Comparisons to treatment with CLiRpath laser catheters, the cited predicate device, indicated that he 2.5 mm Turbo catheter was equivalent with respect to both safety and functionality.

CONCLUSION

A GLP-compliant study using a porcine model verified the safety and performance characteristics for the Spectranetics 2.5 mm Turbo laser catheter when deployed for use in the treatment of peripheral arterial disease. In vitro laboratory tests, as well as qualification and validation studies, have confirmed that 2.5 mm Turbo catheters meet manufacturing and design specifications. All of these data combined establish substantial equivalence to the CLiRpath predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Spectranetics Corpation
c/o Mr. Neil Burris
Clinical Data Services
96 Talamine Court
Colorado Springs, CO 80907

SEP 18 2013

Re: K043465
Trade/Device Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: August 12, 2005
Received: August 15, 2005

Dear Mr. Burris:

This letter corrects our substantially equivalent letter of August 18, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043465

7. Statement of Indication for Use

Device Name: Spectranetics 2.5 mm Turbo™
Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Prescription Use XXXX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043465